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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,704	11/20/2003	Angela Soito	005284.00226	7077

22904 7590 10/13/2006

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EXAMINER

ROY, ANURADHA

ART UNIT PAPER NUMBER

3736

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/716,704	<b>Applicant(s)</b> SOITO ET AL.	
	<b>Examiner</b> Anuradha Roy	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 17-23 and 26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-23 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### **Claim Rejections - 35 USC § 102**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 17-23 & 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Hung et al. (US Patent No. 6,413,228).

Please see prior office action of May 12, 2006 for details of the rejection.

### **Response to Arguments**

Applicant's arguments filed August 1, 2006 have been fully considered but they are not persuasive. Applicant asserts, "The prior art reference of Hung et al. does not disclose each of the elements of the claimed invention arranged as in the present claims." However, Examiner contends Hung et al.'s invention does in fact disclose a system containing a tool for accessing a breast duct (Figure 3); a chart or written guidelines (Column 13, lines 51 - Column 14, line 12 & Column 25, lines 6-33); and lastly an algorithm (Column 26, lines 35-48); *together* to assist in the cytological evaluation of epithelial cells (Column 12, line 56 – Column 13, line 4).

Furthermore, Applicant asserts, "...Hung et al. merely lists several published methods for studying atypical growth patterns of cells. There is simply no mention of charts or written guidelines..." However, given the broadest reasonable interpretation, Examiner contends that the Hung et al. teaches, "the cells can be studied for atypical growth patterns in individual cells and clusters of cells using *published methods*..."

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(Column 13, line 66 – Column 14, line 1),” which anticipates “written guidelines for evaluating the ductal epithelial cells”. Moreover, Hung et al. discloses examples of the published methods disclosing “observed indicia” of the ductal epithelial cells (Column 13, line 5 – Column 42). Thus, Examiner maintains that Hung et al. anticipates “written guidelines for evaluating the ductal epithelial cells,” as claimed.

Applicant further argues, “There is simply no mention of an algorithm for classifying a sample as being normal, atypical or malignant based upon observed indicia” and states, that “the word ‘algorithm’ does not appear anywhere in the specification of Hung et al.” Examiner contends, however, the mere fact that the word “algorithm” does not appear in Hung et al’s specifications does not mean an algorithm, defined as a “a set of rules for solving a problem in a finite number of steps,” (www.dictionary.com) is not disclosed by Hung et al. In fact, Hung et al. does disclose an algorithm for classifying the sample as being normal atypical or malignant based on the observed indicia, by stating the following:

“The morphology of the cells or cellular contents retrieved in the ductal fluid and wash fluid may also be examined. The cellular contents can include, e.g. protein, nucleic acid, or other molecular markers in the cells. Cell morphology can serve to establish whether the ductal epithelial cells are normal (i.e. not precancerous or cancerous or having another noncancerous abnormality), precancerous (i.e. comprising hyperplasia, atypical ductal hyperplasia (ADH) or low grade ductal carcinoma in situ (LG-DCIS)) or cancerous (i.e. comprising high grade ductal carcinoma in situ (HG-DCIS), or invasive carcinoma). Analysis of cell contents may serve to establish similar staging as established by morphology, capturing generally a progression of a precancerous or cancerous condition in the cells” (Column 26, lines 35-48).

Hung et al. further discusses alternative “algorithm[s] to classify the sample...based on the observed indicia” throughout the specification. Thus, Examiner maintains that Hung et al. anticipates an algorithm, as claimed.

### **Conclusion**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later

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than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anuradha Roy whose telephone number is 571-272-6169 and whose email address is anuradha.roy@uspto.gov. The examiner can normally be reached between 9:00am and 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

~AR

  
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